

PROVIDER N.0019P

Best S.r.l.

Via del Trebbio Nord 27/29

Santa Croce sull'Arno PI – Italia

COORDINATOR:

David Di Sandro

Phone: 0571-3835423

Mail: david@laboratoriobest.com

Best S.r.l. has been organizing interlaboratory circuits on a leather matrix in compliance with the ISO /
IEC 17043 standard since 2017.

Schemes for both chemical and physical-mechanical tests using standardized methods (ISO, GB / T,
ASTM) with reference to the matrix are proposed to the participants.

This document describes the statistical techniques and evaluation methods used by Best in
interlaboratory studies.



1. Purpose and field of application of the circuits

Best S.r.l. organizes interlaboratory circuits on leather matrix, the schemes propose both chemical and physical-mechanical tests.

Typical purposes of interlaboratory comparisons include:

- Participant performance evaluation for specific tests or measurements and performance monitoring on an ongoing basis
- Identification of problems and implementation of actions for improvement,
- Personnel qualification
- Definition of the effectiveness and comparability of test or measurement methods
- Additional trust insurance to customers
- Identification of differences between laboratories
- Training of the participating laboratories based on the results of these comparisons
- Validation of statements of uncertainty

No phase of the management of the circuits is subcontracted.

2. Annual program of PTs

Best publishes annually, in the month of September, on the website www.laboratoriobest.com the calendar of all scheduled schemes.

The contents of the PT program are discussed and decided during the meeting between the Quality Manager and the Coordinator, the criteria for the selection of objects and tests are chosen based on the results of previous circuits and programs or any requests from participants.

Best's S.r.l. interlaboratory circuits are arranged in accordance with ISO 13528 and ISO / IEC 17043.

The quantity of sample to be sent to the participants is established each time by the coordinator in relation to the scheme.



3. Interlaboratory studies

Participation in Proficiency tests provides Laboratories with a tool to evaluate and demonstrate the reliability of the data produced and allow them to check routine performance and compare results with those of other laboratories.

Participants in the Proficiency tests receive information on the technical capabilities of their laboratory, useful for the Quality Manager, the Laboratory Manager and the accreditation bodies as an indicator of the degree of analytical competence.

Laboratories can use the results and conclusions provided by the Provider to identify and subsequently resolve the causes that generated divergent results, if any.

Participants will analyze circuit samples with their own routine procedures, standard methods that are used in normal daily practice. The results are collected by Best and statistically processed. The competence of each participant is expressed through the z-score parameter for the chemical tests and the comparison with the median for the solidity tests. The graphs are used to facilitate the interpretation of the data.

4. How to participate

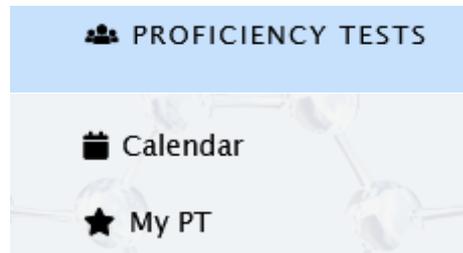
All laboratories and other interested structures, public and private, which carry out the tests covered by the schemes can register in the circuits organized by Best.

The circuits will be activated upon reaching 12 subscribers and the statistical analysis will be conducted with a minimum of 6 valid results.

To participate in a circuit, it is necessary to have access credentials to the "MY PT" portal, therefore:



- ✓ Connect to the website www.laboratoriobest.com,
- ✓ Access the calendar from the “Proficiency test” menu,



- ✓ Click ACCOUNT and fill in the fields present.

At the end of the registration you will be assigned the participant code and you will have access to the portal.

5. MY PT

From the portal you can access the following menus:

- ✚ **My subscriptions** >> summary of the PTs you have joined, the following information is present:

State	PT	Description	Send Samples	Closing Sending Results	Sending Report
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By clicking on the button  you enter the specific scheme in which to insert the conditions of the sample once received, download the instructions to carry out the test and enter results by the expiration date.

- ✚ **Circuits available** >> Calendar of schemes available to make any other registrations
- ✚ **Profile** >> personal and accounting data
- ✚ **Complaints / appeals format** >> the format is available for making appeals, complaints or giving suggestions to the provider.



🚩 **Communications** >> area in which the Provider publishes any general notices for participants (eg changes to dates, circuit cancellation, etc.). Participants are informed by email of the publication of a press release.

6. Confidentiality

Best S.r.l. guarantees that the identity of the participants in an interlaboratory assessment test scheme is known EXCLUSIVELY to the people involved in the execution of the scheme, unless the participant waives confidentiality.

All participant information will be treated as confidential information.

Each participant will be identified by a 4-digit code.

When an interested party asks Best S.r.l. to provide the results of the interlaboratory evaluation tests, participants will be immediately notified.

In the event that a legislative authority requests the results of the interlaboratory evaluation tests, Best S.r.l. will inform all participants.

7. Samples and methods of preparation

The goal is to use materials that ensure close similarity between the evidence in the interlaboratory study and the samples that the participants normally analyze.

The entire batch of the sample selected by the coordinator is completely homogenized and if necessary stabilized and tested for suitability before being sent to the participants.



8. Quality

In Best works qualified and experienced staff able to ensure compliance in the design, preparation, distribution of objects intended for interlaboratory circuits and in the conduct of statistical analysis of the results.

The technicians are qualified and their qualifications are documented.

9. PT management

The management and organization of interlaboratory circuits provides for precise steps that Best implements in accordance with the requirements of the ISO / IEC 17043 standard:

- ✚ Drafting and issuing of the calendar of the proposed schemes,
- ✚ The coordinator carries out the selection of the sample and the verification of homogeneity and stability,
- ✚ Starting the circuit and preparing samples to be sent,
- ✚ Request for confirmation of receipt of the sample and arrival conditions; if not compliant, a new sample will be sent,
- ✚ Submission of results by the participants,
- ✚ Checking the results of the participants to identify obvious errors, for this purpose the data are entered on the form “MOD.AQ007 PG16 Statistical analysis - robust technique”. Calculation of the assigned value using algorithm A of Annex C of ISO 13528 (for chemical tests),
- ✚ Calculation of the assigned value, in the case of physical tests of color fastness, corresponds to the median,
- ✚ Participant evaluation,
- ✚ Drafting of the final report and sending to participants,
- ✚ Issue of certificate of participation and sending to participants.



10. Distribution

In the case of special needs or dangerous goods (low flash point, corrosive, toxic) the distribution of the sample is carried out by a specialized company).

11. Analysis

Best establishes, for each scheme, the method that the participant is obliged to use to perform the test, under penalty of exclusion from participation, it is recommended to treat the sample as routine.

Finally, to ensure that all results are expressed in the same unit of measurement, the participant is bound to enter the data on a format in the private area of the site.

12. Statistical processing of the test results

12.1 Detection of gross errors (chemical tests)

During the four weeks following the sending of the sample, the results of the individual laboratories are collected and about a month after the deadline, the final report is issued and a copy sent to the participants.

12.2 Check the normal distribution of results (chemical tests)

Any aberrant results are identified by calculating the median, values that differ $\pm 50\%$ from the median are discarded from the calculation of the assigned value but the z-score is assigned.

The normality of the data distribution is verified by visual evaluation of the Kernel density to verify the asymmetry and the unimodality.

13. Calculation of the main parameters

In the PVI of the Best S.r.l. processes the results in the following ways:



Valid results <12 or the distribution is bimodal the assigned value is calculated with the median.

The assigned standard deviation is calculated using the standard deviation of the robust median:

$$\text{MADe}(x) = 1,483 \text{ med (of)}$$

where is it:

$$d_i = |x_i - \text{med}(x)|$$

For valid results > 12 and with unimodal distribution, "robust analysis" is applied as indicated in Appendix C, Algorithm A of the ISO 13528: 2016 standard which provides for an iteration of the values of x^* and s^* as described below starting from the value of the Median (x^*)

Median (x^*)

$$x^* = \text{median of } x_i \quad (i = 1, 2, \dots, p)$$

Scarto tipo robusto (s^*)

$$s^* = 1,483 \text{ median of } |x_i - x^*| \text{ with } (i = 1, 2, \dots, p)$$

$$\sigma = 1.25s^*$$



For each x_i ($i = 1, 2, \dots, p$), calculate:

$$x_i^* = \begin{cases} x^* - \delta & \text{when } x_i < x^* - \delta \\ x^* + \delta & \text{when } x_i > x^* + \delta \\ x_i & \text{otherwise} \end{cases}$$

Calculate the new values of x^* and s^* from:

$$x^* = \sum_{i=1}^p x_i^* / p$$

$$s^* = 1,134 \sqrt{\sum_{i=1}^p (x_i^* - x^*)^2 / (p-1)}$$

The x^* and s^* values are continuously updated with an iterative process that applies until the algorithm has converged, i.e. until the new values of x^* and s^* have no differences on the third significant digit between an iteration and the next.

At this point x^* becomes the assigned value.

The following parameters are also calculated from this analysis:

- σ_{pt} (assigned standard deviation); obtained from the relative standard deviation (%), predetermined and defined in the planning stage.
- $u(x_{pt})$ (uncertainty of the assigned value) which is equal to $1.25 s^* / \sqrt{p}$ (s^* represents the robust standard deviation of the results and p the number of such results)

1) If the CV% is not present in the official methods, but reproducibility data are available, the following formula is used to obtain it:

$$\sigma R = \frac{R}{2,8}$$

$$CV\% = \frac{\sigma R}{conc.} \times 100$$

σR = standard deviation of reproducibility



R = reproducibility

CV = coefficient of variation

Conc. = Analyte concentration in the official method

If the CV% or other precision data (Reproducibility, Standard deviation of Reproducibility) are not present in the official methods, it is defined by the organizer based on the matrix and concentrations to be determined based on their experience. The laboratory arranges PTs at concentrations as close as possible to a range of values found in common samples.

The organizer can use the same CV% used in the previous PT for the same test on the same type of matrix.

Based on the performance of the circuits, the PTP verifies that the CV% defined in the planning phase is suitable for the method applied, this can be deduced from the comparison with the robust CV%, if the latter is lower than the default CV%, the organizer in the next PT evaluates whether to define a narrower CV% in order to increase the performance of the participants.

In the event that the robust CV% is greater than the default CV%, the organizer evaluates the possibility of increasing the default CV% by checking its adequacy.

$$\sigma_{pt} = \frac{x_{pt} \cdot CV\%}{100}$$

Best has established that the expression of the CV value must be a whole number, therefore results with decimans are rounded according to the common rounding rule "by access and by default".

Calculation z-score

$$z = \frac{(x_i - x_{pt})}{\sigma_{pt}}$$



z-score

x_i = laboratory result

x_{pt} = assigned value

σ_{pt} = assigned standard deviation

$|Z| \leq 2$ "Acceptable"

$2 < |Z| \leq 3$ "Questionable"

$|Z| > 3$ "Not Satisfactory"

The uncertainty of the assigned value was calculated using the following formula:

$$u(x_{pt}) = 1,25 s^* / \sqrt{p}$$

$u(x_{pt})$ = uncertainty of the assigned value

s^* = robust standard deviation of the data

p = number of results

The robust standard deviation s^* is calculated according to algorithm A (ref. Par. C.3 of Annex C of ISO 13528)

If the condition $u(x_{pt}) \leq 0.3 \sigma_{pt}$ is not met, the z score that is used is the z 'score

$$z' = \frac{(x_i - x_{pt})}{\sqrt{\sigma_{pt}^2 + [u(x_{pt})]^2}}$$

For the physical tests of color fastness, a statistical technique of perception by internal experts is used (ref. 8.2 of ISO 13528), all the results transmitted by the participants are taken into account and the organization calculates the median.

The median in this case is the assigned value.



14. Performance Evaluation

A laboratory that participates in a PVI for chemical tests has as its primary interest the evaluation of the accuracy of the data it produces. Each laboratory will in fact receive a numerical indication (z-score) that will allow you to evaluate its performance. Participants are not aware of the assigned value until the report is issued.

In accordance with the provisions of ISO 13528, the performance of the laboratory (for chemical tests) will be considered "acceptable" only when the value of z (or z ') is $|Z| \leq 2$.

Values outside this range are reported in the PVI Report with the annotation:

- W (Warning), if the value $2 < |Z| \leq 3$
- A (Action), if the value is > 3

For physical tests of color fastness (qualitative ordinal) the evaluation of the participants takes into consideration the results that deviate from the median value of at least 1 ($>$ by 1 or $<$ 1 ordinal unit) and are marked with an X, this identifies a unsatisfactory result (warning).

In this case, the laboratory is required to take corrective action.

If the calculation of the median (number of even results) results between two ordinal units, the largest ordinal unit is assumed as the median.

Being a qualitative test, it does not provide for the calculation of uncertainty.

14.1 Graphs

The graphical presentation of the results used in the reports depends on the type of interlaboratory circuit.

Best usually uses:



Kernel density: In statistics, kernel density estimation (KDE) is a non-parametric way to estimate the probability density function of a random variable.

Histograms: For physical tests on the PVI ratio, the results of each participant compared to the calculated median line are illustrated by means of histograms.

15. Reports

The interlaboratory assessment test reports have a standardized format in line with the paragraphs required by the ISO / IEC 17043 standard:

Best's PVI Report includes:

- The name, function and signature of the person who authorized the relationship,
- The date of issue and the status of the report,
- Indication of the level of confidentiality of the results,
- The number of the report and the full title of the scheme to which it refers,
- Description of the objects of the interlaboratory evaluation tests, including the data necessary for the preparation of these objects and an evaluation of homogeneity and stability,
- The results of the participants anonymously,
- Statistical data and summaries, including assigned values and the range of acceptable results and graphical representations,
- The procedures used to define each assigned value,
- The metrological traceability data and the measurement uncertainty of each assigned value,
- The procedures used to determine the standard deviation for the assessment of competence,
- Information on the development and implementation of the interlaboratory assessment test scheme
- Comments and recommendations, based on the outcome of the PT.

16. Complaints and appeals



In the private area, in the "complaints / appeals" section, it is possible to appeal in relation to the final outcome provided by Best and the performance evaluation, or make suggestions regarding the organizational management of the schemes.

17. Questionnaire

Feedback from participants is welcome in order to actively contribute to the development of the scheme and to the improvement of the provider, therefore there is also the questionnaire section to be filled in at the end of the scheme